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09/186,810 11/05/98 CARLYLE

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EXAMINER

PREBILIC, P

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 08/24/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**09/186,810**

Applicant(s)  
**Carlyle et al**

Examiner  
**Paul Prebilic**

Art Unit  
**3738**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jun 18, 2001
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 4, 8-17, and 28 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 8-13, 15-17, and 28 is/are rejected.
- 7) ☒ Claim(s) 14 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other:

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 8, 9, 11, 12, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Cahalan et al (US 5,308,641) wherein the glutaraldehyde crosslinking agent attaches to the growth factor biomolecule and to the spacer attached to the substrate; see the whole document, especially the abstract, column 4, lines 20-43 and column 6, lines 8-28.

Claim 28 is rejected under 35 U.S.C. 102(b) as being anticipated by Rodman (US 5,606,026). Rodman anticipates the claim language where the 2 mm strips are the substrate(s) as claimed; see the whole document, especially column 16, lines 28-39.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cahalan et al (US 5,308,641) in view of Goldstein (US 5,613,982). Cahalan et al disclose the use of human tissue and animal tissue as the implant substrate material but fail to disclose the specific types of animal tissue therefor. Goldstein, however, teaches that it was known to use porcine tissue for similar implants. Hence, it is the Examiner's position that it would have been obvious to use porcine tissue as the tissue substrate of Cahalan et al in order to reduce the cost of the implant and in order to reduce the risk of disease transmission to human beings upon implantation.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cahalan et al (US 5,308,641) in view of Robertson et al (US 3,755,042). Cahalan et al meet the claim language except for the sterilizing and packaging of the implant as claimed. Robertson et al, however, teaches that sterilizing and packaging of medical materials for distribution has been known to the art. Therefore, it is the Examiner's position that it would have been obvious to an ordinary artisan to sterilize and package the Cahalan et al device so that patients all over the world could benefit from it.

Claims 13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cahalan et al (US 5,308,641) in view of Bayne et al (EP 0476983).

With regard to claim 13, Cahalan et al fail to disclose the use of VEGF even though many other growth factors are listed for use therewith. Bayne et al, however, teaches that the claimed VEGF growth factor has been known and used in the same art in a very similar fashion. Hence, it is the Examiner's position that it would have been obvious to an ordinary artisan to use VEGF as

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the growth factor of Cahalan et al so that such an implant could be successfully implanted inside the vascular regions of the body.

With regard to claim 16, Cahalan et al do not disclose the process of culturing cells onto the implant as claimed. Bayne et al teaches that it was known to the art to do so at the time the present invention was made. Hence, it is the Examiner's position that it would have been obvious to pre-seed or culture cells onto the Cahalan et al implant for the same reasons Bayne et al does the same and in order to control the types of cells which grow in the implant.

#### *Allowable Subject Matter*

Claim 14 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### *Response to Arguments*

Applicant's arguments filed June 18, 2001 have been fully considered but they are not persuasive except with respect to Rodman and the set of claims with claim 1 as their base. Specifically, Applicants argue that the specific controls of the process result in active growth factor. However, Applicants disclose "non-specific crosslinking to bind VEGF to the biocompatible material"; see page 17, lines 12-15 of the specification. Furthermore, the claims set forth nothing with regard to the activity of the bound growth factor, and thus, the argument is not commensurate with the scope of the claims. Additionally, there is no demonstration that the

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Cahalan et al growth factor and their means of attachment prevents association of viable cells while the presently claimed equivalent promotes the same. Finally, there is no evidence of record that the present invention has improved activity while the Cahalan et al invention does not. For this reason, Applicants' assertion is considered to be a mere allegation.

With respect to the traversal of the Rodman rejections, the Examiner posits that the arguments were persuasive with respect to claim 1 and its dependent claims but not with respect to claim 28. Specifically, claim 28 does not require binding of the Tat protein to the substrate. For this reason, the argument that the claims are not anticipated by Rodman is not persuasive since claim 28 requires that the Tat protein be associated with the substrate. Since Rodman teaches a form of association of the Tat protein with a substrate, the claim language is fully met in this regard and reads on the claim as a whole. For this reason, the rejection of claim 28 has been maintained.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 305-3580.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic  
Primary Examiner  
Art Unit 3738